Trends In Amplification

VOLUME 6, NUMBER 2, 2002

BAHA®: The Direct Bone Conductor

Patrik Westerkull, MSc (EngPh)

The BAHA® device uses the principle of direct bone conduction (DBC) to overcome several of the drawbacks of conventional air-conduction (AC) and bone-conduction (BC) hearing aids for patients with conductive or mixed hearing loss. Recent developments of the BAHA system have made it more user friendly and the device has been further miniaturized. The FDA has cleared the device for both adults and pediatrics (from age 5 and up) and also for bilateral fitting.

With the BAHA system, a vibrating transducer is directly connected to the skull bone, of which the cochlea is an integrated part. This principle of DBC provides a more or less direct and clear transmission pathway to the cochlea. The BAHA surgery is, however, a minor surgical procedure and does not in any way interfere with the hearing organ so there are no risks of damaging the ear or the residual hearing. Scientific papers about BAHA from around the world report high performance, safety, and patient satisfaction. (Tjellström and Granström, 1995; Powell *et al.,* 1996; Hartland *et al.,* 1996; Papsin *et al.,* 1997; Tietze *et al.,* 2000; Tjellström and Håkansson, 2001; Snik *et al.,* 2001; Lustig *et al.,* 2001). Today, more than 9000 patients around the world have been treated with BAHA.

Description of the Device

The BAHA system (Figure 1) consists of a small titanium fixture that is surgically implanted in the temporal bone behind the ear, where it bonds to the living bone through osseointegration. A skin-penetrating abutment is then attached to the fixture. The installation is a straightforward and minor surgical procedure, which in most cases is performed under local anesthesia. After surgery, the implant will be left without loading during a period of around 3 months in adult patients. During this time, osseointegration between the living bone and the titanium fixture takes place. The skin-penetrating area has to be correctly prepared during surgery to facilitate a good hygiene around the abutment and to ensure a long-term reaction-free skin penetration. The clinical safety and high success rate of this technique has been reported in numerous of scientific articles (Tjellström and Granström, 1995; Reyes *et al.,* 2000).

After the osseointegration period, the sound processor can be fitted. Patients can easily connect and disconnect the sound processor from the abutment at will (see Figure 2). The coupling between the sound processor and the skin-penetrating abutment transmits the vibrations to the os-

Entific Medical Systems AB, Box 16024, 41221 Gothenburg, Sweden
email patrik.westerkull@entific.com

©2002 Westminster Publications, Inc., 708 Glen Cove Avenue, Glen Head, NY 11545, U.S.A.

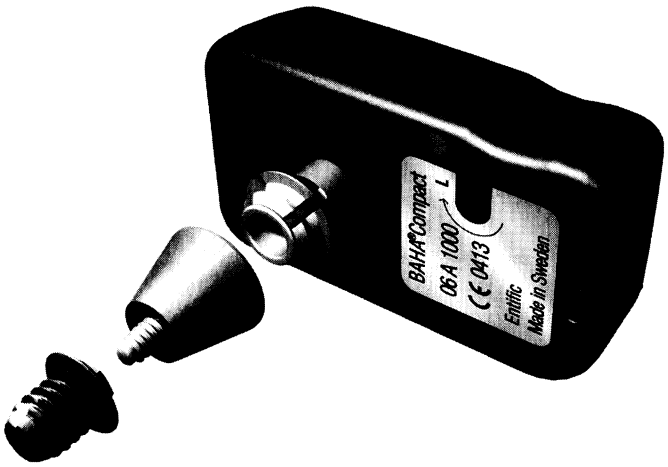

Figure 1. The BAHA® system consists of a small titanium fixture with a skin-penetrating abutment and a sound processor with a snap coupling.

seointegrated fixture in the bone, but it is also an important safety consideration since it will release the sound processor from the abutment in case it is struck. This connection results in a direct and stable mechanical transmission link between the vibrating transducer in the sound processor and the fixture which is integrated with the skull bone (Figure 3). This link can, without any measurable damping or distortion, transfer audio frequencies from the transducer to the skull bone. The signal will bypass the middle ear and stimulate the cochlea as bone conduction sound. Therefore, the degree of the conductive hearing loss is irrelevant for the audiological performance of the BAHA.

Three different models of the BAHA sound processor are available. The BAHA® Classic 300 and the BAHA® Compact models are ear-level models and the BAHA® Cordelle II is a body-worn power model. Both the ear-level models include a microphone, battery compartment, amplifier electronics, vibration transducer, adjustment controls, and an electrical input connector. The BAHA® Classic 300 is the basic model and has linear amplification. The battery is a standard zinc-air battery, size 675 and lasts approximately 1 to 3 weeks.

The BAHA® Compact is the new smaller model, which was introduced early in 2001. It is around 30% smaller than the Classic 300, and has output compression, AGCo, and includes a new output amplifier. The Compact suppresses interference from cellular phones so the patient can use a cellular phone in the conventional manner.

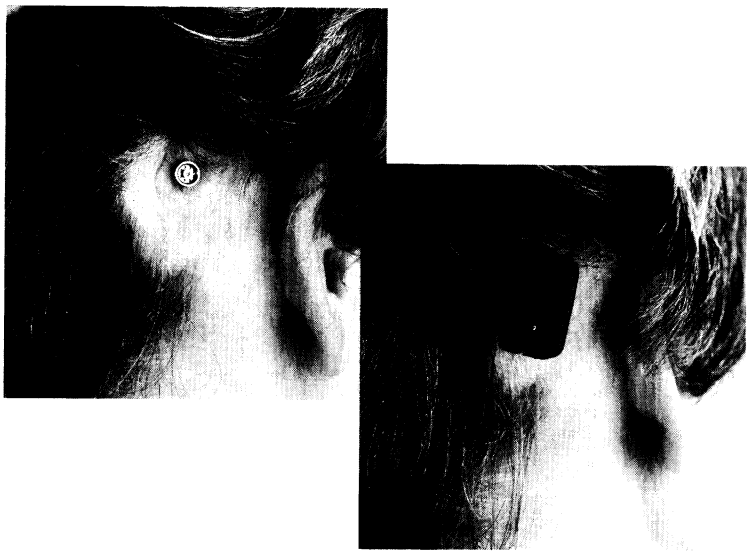

Figure 2. The left picture shows the BAHA abutment in place. The right picture shows the BAHA® Compact model connected to the abutment. The BAHA device can be easily connected and disconnected to the abutment.

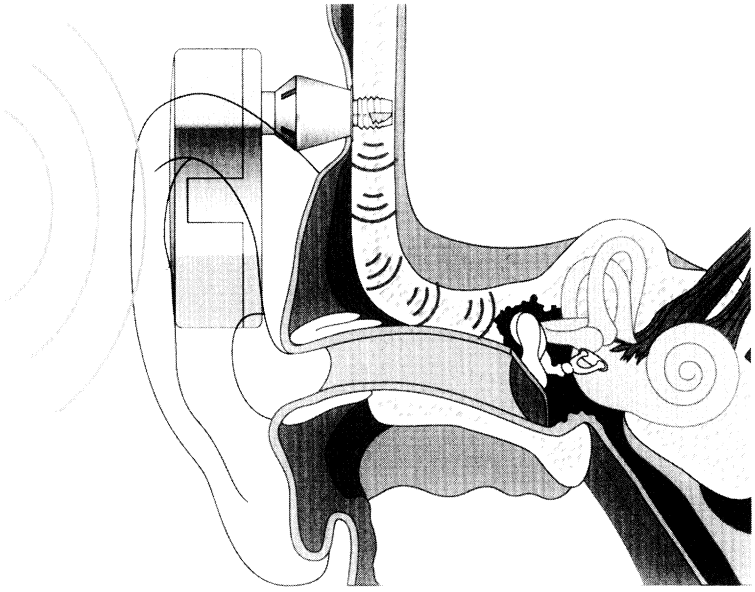

Figure 3. The vibrations from the sound processor are transferred via direct bone conduction directly to the skull, bypassing the middle ear and stimulating the cochlea as direct bone-conduction sound.

The Compact is powered by a standard zinc-air battery, size 13. The battery lasts approximately 1 to 2 weeks.

The BAHA® Cordelle is a more powerful model that consists of a head-worn transducer connected by a cord to a body-worn amplifier. The body-worn amplifier includes a compression amplifier, microphone, and a telecoil function. The Cordelle is powered by a 9V rechargeable battery (IEC 6F22).

All BAHA models have an electrical input connector to which accessories like FM-systems, audio adapters, and telecoil units can be connected.

A unique feature with the BAHA system compared to other partly implantable devices is that the patient candidates can be preoperatively evaluated with the device. The sound processor is then connected to a test rod or a test headband, which is pressed against the skull. With this arrangement, the sound quality will not be as good as with the osseointegrated fixture in place since there will be damping, of especially high frequencies, through the skin. It is still, however, an important, effective, and simple way to evaluate BAHA candidates.

What BAHA Can Offer

BAHA is suitable for patients having a conductive or mixed hearing loss. The conductive hearing loss might be caused by a chronic infection, so the ear might be draining or the patient might have undergone a radical mastoid cavity surgery. If an AC hearing aid is fitted, the ear canal is occluded and the infection and drainage may be aggravated. Since the AC device has to be quite powerful, the patient may also complain about problems with feedback and poor sound quality.

BAHA can offer these patients sound quality at least as good as the AC device, but, more importantly, the ear is not occluded, which gives an opportunity for the infection to heal, and feedback and discomfort problems will likely resolve.

A conductive hearing loss might also be caused by the lack of an ear canal (auricular atresia) due to a congenital malformation. Traditionally, these patients have been helped with an old-fashioned bone conductor on a steel spring headband or included in eyeglass frames.

These devices have several drawbacks: (1) The sound quality is poor, largely due to the damping of high frequencies when passing

through the skin; (2) the patients complain about pain and headache due to the constant pressure of the spring headband; (3) the poor aesthetics. BAHA can offer these patients a significantly better sound quality, excellent wearing comfort, and a better aesthetic result. Patients with a pure sensorineural hearing loss who have difficulties wearing an earmold due to eczema, or other outer ear conditions, may also benefit from a BAHA.

Audiological Indications

BAHA® Classic 300 (ear level device)

The indications for BAHA® Classic 300 is a pure tone average bone conduction threshold better than or equal to 45 dB HL at 0.5, 1, 2 and 3 kHz. Note that the BAHA system works independent of the function of the middle ear, so a patient who has a maximum conductive hearing loss of 60 dB HL and on top of that a sensorineural component of 40 dB HL, may have an air conduction threshold of 100 dB HL, ie, a very severe hearing loss.

BAHA® Compact (ear level device)

The BAHA® Compact has the same indications as the BAHA® Classic 300. The Compact has the same gain as the Classic 300 for input levels lower than 60 dB HL, however the Compact utilizes output compression (AGCo). The compression reduces the gain for loud sounds and therefore limits distortion. This gives the Compact better sound comfort, particularly for loud sounds, although some patients may not find it "loud" enough in certain situations and may still prefer the Classic 300.

BAHA® Cordelle II (body-worn model)

The body-worn BAHA model, BAHA® Cordelle II, has a nominal output, which averages 13 dB stronger than the Classic 300 and Compact (measured at 0.5, 1, 2, 3 kHz). The BAHA® Cordelle is intended for even more severe mixed hearing losses. A more exact recommended fitting range for the device is still to be determined.

Other Exclusion Criterias

Patients who cannot maintain a normal daily hygiene using soap and water are not good candidates for a BAHA due to the higher risk of skin infections. Careful consideration must be given to the patient's psychological, physical, emotional, and developmental capabilities to maintain hygiene. The device is not cleared by the FDA for children under the age of 5 years.

Clinical Results

Over 100 published scientific articles from around the world have reported the benefits of and clinical success with BAHA treatment. The reports have investigated everything from surgical and medical considerations, technical aspects, audiometric results, and patient satisfaction questionnaires. Audiological results with BAHA are compared with the unaided situation, as well as with AC hearing aids and BC hearing aids.

Surgical Aspects

Several scientific articles on surgical and clinical aspects, such as fixture success rate and possible skin infections, have been published. The fixture success, at 97%, has proven to be very high (Mylanus *et al.,* 1994).

Tjellström and Håkansson (1995) reported in a 5-year follow up study that only 5 of 149 implants were lost. No severe medical problems caused by a fixture loss have been reported. The most common reason for fixture loss is trauma, and this complication is therefore more common in children than adults. An effect of a fixture loss is that the patient is not able to wear the BAHA for a short period, because a new fixture must be implanted and osseointegration again needs to take place prior to use of the external sound processor.

The frequency of adverse skin reactions around the skin-penetrating abutment has been studied at several clinics. Tjellström and Håkansson (1995) report that there were no adverse skin reactions in 96.4% of 806 observations. Van der Pouw *et al.,* (1999a) reports that during 1257 observations there were no adverse skin reactions in 91% of the cases. The observed adverse skin reactions were mainly a redness, which in most cases can be solved by improved patient hygiene around the abutment.

Audiometric Results

In comparison with traditional BC hearing aids, BAHA shows significant improvements in terms of free-field thresholds and speech-recognition in noise. In one of the first larger studies (Håkansson *et al.,* 1994) audiometric measurements were obtained for both unaided, aided with BC hearing aids and the BAHA. The results with BAHA in all tests were considerably better than the unaided condition, and significantly better than the conventional BC hearing aid. For example, the discrimination of monosyllabic phonetically balanced words was measured in a sound field at 63 dB SPL, with a background noise at 57 dB SPL. In 110 patients measured, audiometric results showed that sound field speech recognition was improved an average of 6.2% with the BAHA compared to the BC device.

Van der Pouw *et al.,* (1999b) found a mean improvement of the average free-field tone threshold (at 0.5, 1, 2 and 4 kHz) for all 89 patients to be around 5 dB better with BAHA compared to conventional BC device (see Figure 4). Cooper *et al.,* (1996) also reported significant improvements in free-field warble-tone thresholds with BAHA, compared with conventional BC aids. Pediatric results (Powell *et al.,* 1996) demonstrate an improvement of the mean free-field warble-tone threshold of around 14 dB with the BAHA, compared to both AC and BC alternatives.

In comparisons with traditional AC hearing aids, BAHA shows similar, or slightly improved, audiometric results (Cooper *et al.,* 1996; Mylanus *et al.,* 1998). Mylanus *et al.,* (1998), reports that the improvement in S/N ratio between the BAHA and AC hearing aids was 1.1 ± 2.1 dB. Although the audiometric improvements with BAHA for these patients are rather small, an AC hearing aid does not offer an acceptable solution since an earmold will just aggravate the infection in the ear and, in some cases, cause feedback and discomfort problems.

Patient Satisfaction

The subjective opinions about improved sound quality and overall satisfaction (see Figure 5), as well as the number of user hours per day, are very high for BAHA patients. On average, 80% use their BAHA more than 8 hours per day. Scientific studies on patient satisfaction have been reported by Cooper *et al.,* (1996), Powell *et al.,* (1996), Wazen *et al.,* (1998), and Lustig *et al.,* (2001). Figure 6 shows results according to Cooper *et al.,* (1996). The satisfaction in this study was higher with BAHA among patients who were suffering from congenital malformations and who had previously worn a traditional BC device compared to patients who were suffering from chronic suppurative otitis media and who previously had worn an AC device.

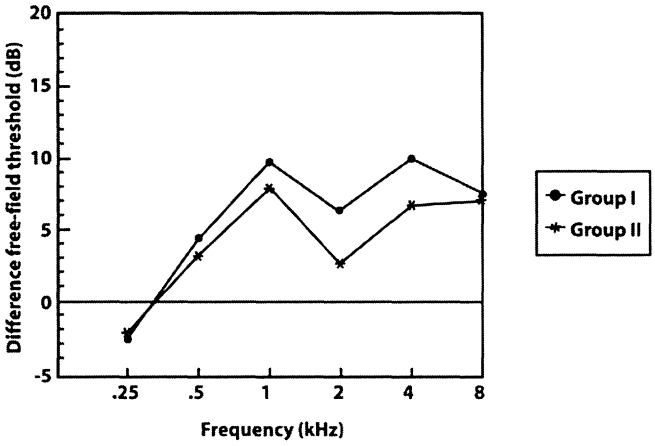

Figure 4. Average improvements of the aided free-field tone thresholds with BAHA compared to conventional bone conduction hearing aids, according to van der Pouw et al., 1999. Group I consists of 32 patients who have worn BAHA for 5 years or longer. Group II consists of 57 patients who wore their BAHA for less than 5 years.

Bilateral Fitting

Bilateral fitting of BAHA has proven to contribute to improvements regarding sound localization and speech recognition in noise. The benefits of bilateral BAHA fittings are reported by Bosman *et al.,* (2001). The improvements in percentage of correct answers on localization within a 30° angle, with 500 Hz noise bursts increased from 55% for unilateral fitting to 90% with bilateral fitting, and with 2 kHz noise bursts, from 58 % for unilateral fitting to 90% with bilateral fitting. The performance is most likely results of the binaural pick-up and stimulation positions, and the difference in transmission and attenuation of the vibrations in the skull to the two cochleas.

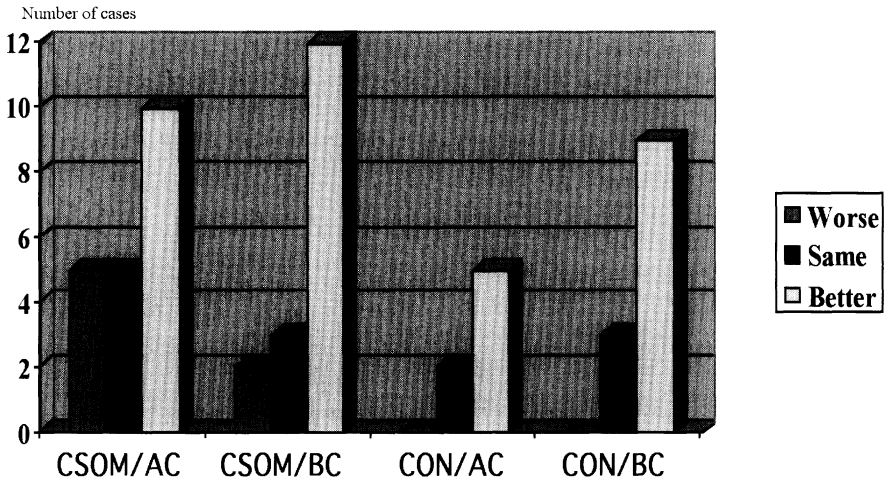

Figure 5. Histogram showing the reported overall satisfaction with BAHA, compared to the previous aid, for each patient group. CSOM/AC-patients with chronic suppurative otitis media who previously used an air conduction aid; CSOM/BC-CSOM patients previously using a bone conduction aid; CON/AC-patients with congenital atresia previously wearing an air-conduction aid; CON/BC-atresia patients previously using a bone conduction aid. (Cooper *et al.,* 1996)

New Clinical Indications for BAHA

One type of hearing loss that has often been overlooked is the unilateral hearing loss. This is partly because this type of hearing loss has been regarded as a less severe handicap and probably partly because, until now, there has not been a good treatment option to offer these patients. The only possible solution so far has been a traditional contralateral routing of signal (CROS) hearing aid. Unfortunately, this system is limited in terms of performance, and in addition, the handling and aesthetics are considered to be poor. Because of this, most patients refuse to wear a traditional CROS aid.

The unilateral loss can be either conductive or sensorineural and can also take the form of different types of mixed losses.

Patients with a unilateral conductive hearing loss still have two well functioning cochleas. Their medical background could, for example, be chronic otitis or a congenital malformation. If a BAHA is placed on the poor side, the vibrations from the device will primarily stimulate the cochlea on that side. The vibrations will also travel through the skull to the contralateral cochlea, although the signal will be somewhat more attenuated from travelling through the skull. The cochlea of the good ear will, however, mainly pick up sound via normal air conduction. The sound is picked up at two different locations, ie, in the microphone of the BAHA and at the eardrum of the normal ear. In this situation, the two cochleas will be mainly receiving two different signals, so the patient is likely to get stereophonic hearing.

Chasin (1998) studied seven patients with unilateral conductive hearing loss who were fitted with BAHA. Significant improvements with masking level difference in sound field, as well as the speech perception in noise, were observed.

Snik *et al.,* (2002) reported significantly improved sound localization in six of the eight patients involved in the study. The sound localization was tested with a (half) circle of loudspeakers, separated by 30° each. The mean absolute error (MAE) per measurement condition was the outcome measure where a MAE value of 0 means perfect localization.

Wazen *et al.,* (2001) reported the subjective patient satisfaction for a patient group of eight patients with unilateral conductive hearing losses. According to the discussion in the article, all patients were satisfied with the outcome. With the Hearing Handicap Inventory for Adults (HHIA),

five of the patients reported that while using the BAHA their difficulty in daily living decreased from "severely" handicapped to a handicap of "mild to none." The other three patients reported an unchanged or increased handicap level with the HHIA. According to the author, the HHIA might however not be an ideal measure to identify the problems for unilateral listeners. The patient numbers in these studies are still quite low, and further studies including more patients are necessary to verify the effectiveness of the treatment for this patient group.

Another hearing loss is unilateral profound sensorineural deafness, often just referred to as single-sided deafness. The medical background can be, for example, an acoustic neuroma. In this situation, BAHA would have to work as a bone conduction CROS device transmitting the signal from the deaf side through the skull to the contralateral cochlea. Only one working cochlea will pick up sound, both in the natural way via air conduction and as bone-conduction vibrations generated from the BAHA device. A number of issues are raised when discussing these patients. Will, for example, the BAHA be strong enough to overcome the transcranial attenuation? Will the patients experience a real benefit from the device and will it offer them a better treatment option than traditional CROS hearing aids? More conventional traditional CROS solutions like AC CROS and transcranial AC CROS aids are used very little clinically due to poor esthetics and performance.

An international multi-center study with clinics from eight countries has been initiated and is currently investigating the benefit of BAHA for patients with unilateral profound sensorineural deafness. Improvements of the head-shadow effect and hearing in noise are being measured. Subjective measurements include established questionnaires to gain a complete picture of possible benefits.

Initial studies are being prepared for publication. So far, the results from some centers have been presented at scientific conferences. For example Somers *et al.,* from Antwerpen, Belgium, presented the results for eight single-sided deaf patients fitted with BAHA at the 23rd Meeting of the Politzer Society (2002). They concluded that the BAHA eliminates the head-shadow effect and that the overall patient satisfaction was high. At the 2002 American Academy of Audiology meeting, a poster presentations by Cox *et al.,* from John Hopkins, Baltimore, MD reported further positive results on this topic. If research continues to show good results, BAHA might open up a new way to help these patients and, for the first time, to offer them appropriate treatment.

From a hearing research point of view, it is quite exciting to see how skull attenuation is both sufficient to allow bilateral BAHA fittings for traditional BAHA patients, and at the same time, the attenuation is not too high to allow the BAHA to work as a CROS device.

Technical Developments

BAHA patients have mainly a conductive hearing loss, so the need for compression should be less than for patients suffering from a pure sensorineural hearing loss since the dynamic range is then still fairly large for BAHA patients. However, some compression has been shown to be very useful to improve the overall sound comfort and quality also for BAHA patients . The BAHA® Compact model that was introduced early in 2001 has an output compression circuit. During spring 2003, a digital version of the BAHA will be introduced. Directional microphones and further miniaturization of the device are also planned for the future. A miniaturized plug-in module, with a directional microphone for the BAHA® Compact, will be introduced after summer 2002.

A fully implantable BAHA has not yet been planned because it would include a major challenge in feedback control since BAHA is vibrating the whole skull and another challenge with the power supply. The current BAHA concept has the substantial advantage that no electronics or active components are implanted into the patient's body. This gives a highly reliable and cost efficient system where the device can be easily taken off, upgraded, adjusted, or sent in for repair, if necessary.

References

Bosman AJ, Snik AFM, van der Pouw CTM, Mylanus EAM, Cremers CWRJ. Audiometric evaluation of bilaterally fitted bone-anchored hearing aids. Audiology 40:(3)158-167, 2001.

Chasin M, Wade P. Fitting of bone anchored hearing aids on unilateral conductive hearing losses. Hearing Rev 42-43:1998.

Cooper HR, Burrell SP, Powell RH, Proops DW, Bickerton JA. The Birmingham bone anchored hearing aid programme: Referrals, selections, rehabilitation, philosophy and adult results. J Laryngol Otol (Suppl. 21): 13-20, 1996.

Hartland S, Proops DW. Bone anchored hearing aid wearers with significant sensorineural hearing losses (borderline candidates): Patients' results and opinions. Journal Laryngol Otol (Suppl. 21):41-46, 1996.

Håkansson B, Carlsson P, Tjellström A, Lidén G. The bone-anchored hearing aid: Principal design and audiometric results. ENT Journal 73:(9)670-675, 1994.

Lustig LR, Alexander Arts H, Brackman DE, Francis HF, Molony T, et al. Hearing rehabilitation using the baha bone-anchored hearing aid: Results in 40 patients. Otol Neurotol 22:(3)328-334, 2001.

Mylanus EAM, Cremers CWRJ. A one-stage surgical procedure for placement of percutanus implants for the bone-anchored hearing aid. J Laryngol Otol 108:1031-1035, 1994.

Mylanus EAM, van der Pouw CTM, Snik AFM, Cremers CWRJ. Intraindividual comparison of the bone anchored hearing aid and air-conduction hearing aids. Arch Otolaryngol Head Neck Surg 124:(3)271-276, 1998.

Papsin BC, Sirimanna TKS, Albert DM, Bailey CM. Surgical experience with bone-anchored hearing aids in children. The Laryngoscope 107:(6)801-806, 1997.

Proops DW. The Birmingham bone anchored hearing aid programme: Surgical methods and complications. J Laryngol Otol (Suppl. 21):7-12, 1996.

Powell RH, Burell SP, Cooper HR, Proops DW. The Birmingham bone anchored hearing aid programme: Paediatric experience and results. J Laryngol Otol (Suppl. 21):21-29, 1996.

Reyes RA, Tjellström A, Granström G. Evaluation of implant losses and skin reactions around extraoral bone-anchored implants: A 0- to 8-year follow-up. Otolaryngol Head Neck Surg (122):272-276, 2000.

Snik AFM, Mylanus EAM, Cremers CWRJ. The bone-anchored hearing aid, a soultion for previously unresolved otologic problems. Otalaryngol Clin North Am 34:(2)365-372, 2001.

Snik AFM, Mylanus EAM, Cremers CWRJ. The bone-anchored hearing aid in patients with a unilateral airbone gap. Otol Neurotol 23:(1)61-66, 2002.

Tietze L, Papsin B. Utilization of bone-anchored hearing aids in children. Int J Pediatr Otorhinolaryngol 58:75-80, 2001.

Tjellström A, Håkansson B. The bone-anchored hearing aid. Design, principles, indications and long-term clinical results. Otalaryngol Clin North Am 28:(1)53-72, 1995.

Tjellström A, Granström G. One-stage procedure to establish osseointegration: A zero to five years follow-up report. J Laryngol Otol 109:593-598, 1995.

Tjellström A, Håkansson B. Bone-anchored hearing aids, current status in adults and children. Otalaryngol Clin North Am 34:(2)337-364, 2001.

Van der Pouw CTM, Mylanus EAM, Cremers CWRJ. Percutaneous implants in the temporal bone for securing a bone conductor: Surgical methods and results. Ann Otol Rhinol Laryngol 108:(6)532-536(a), 1999.

Van der Pouw CTM, Snik AMF, Cremers CWRJ. The BAHA HC200/300 in comparison with conventional bone conduction hearing aids. Clin Otolaryngol 24: (3)171-176(b), 1999.

Wazen JJ, Caruso M, Tjellström A. Long-term results with the titanium bone-anchored hearing aid: The U.S. experience. Am J Otol 19:(6)737-741, 1998.

Wazen JJ, Spitzer J, Ghossani SN, Kacker A, Zschlommer A. Results of the bone-anchored hearing aid in unilateral hearing loss. Laryngoscope 111:(6)955-958, 2001.